

EXHIBIT 10

1 - - -
2 : SUPERIOR COURT OF
3 : NEW JERSEY
4 IN RE: : LAW DIVISION -
5 PELVIC MESH/GYNECARE : ATLANTIC COUNTY
6 LITIGATION :
7 : MASTER CASE 6341-10
8 :
9 : CASE NO. 291 CT
10 CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF
11 CONFIDENTIALITY
12 - - -
13 November 2, 2012
14 - - -
15 Transcript of the deposition of
16 VINCENT R. LUCENTE, MD, called for Videotaped
17 Examination in the above-captioned matter, said
18 deposition taken pursuant to Superior Court Rules of
19 Practice and Procedure by and before Ann Marie
20 Mitchell, a Federally Approved Certified Realtime
21 Reporter, Registered Diplomate Reporter, Certified
22 Court Reporter, and Notary Public for the State of
23 New Jersey, at Regency Towers, 1600 Lehigh Parkway
24 East, Allentown, Pennsylvania, commencing at 9:50 a.m.
25 - - -

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1 different physician, they had zero. So if you
2 look -- and the constant was the Prolift® mesh. The
3 constant was the kit and the delivery instruments.
4 But we had one center having every single patient
5 having an exposure and another center having zero.

6 Q. Is it fair to say you know of
7 multiple hospitals where they have implanted the
8 Prolift® where they had close to or if not
9 100 percent of exposure rate, mesh exposure after
10 Prolift® implantation?

11 MR. SNELL: Objection, form.

12 THE WITNESS: I know some of them,
13 again, the 100 percent is sort of a striking number.
14 That, to me, clearly shows a clear problem.

15 So it does vary, and that's the
16 extreme variation. I believe that with proper
17 technique, that the exposure rate, whether the mesh
18 comes in abdominally or it comes in vaginally, it
19 should be in the range of about 5 to 6 percent or
20 perhaps lower.

21 BY MR. MAZIE:

22 Q. That's not my question.

23 My question was, you're aware of
24 numerous hospitals where the exposure rate was above
25 20 percent, the mesh exposure rate after

1 implantation of the Prolift®?

2 A. I would say --

3 MR. SNELL: Object to form.

4 THE WITNESS: -- I'm aware of
5 several, not numerous.

6 BY MR. MAZIE:

7 Q. As you sit here today, you can't tell
8 us what the exposure rate has been up to date,
9 today, for mesh exposure for people who have had the
10 Prolift®?

11 MR. SNELL: Objection, form.

12 THE WITNESS: For every patient who
13 has had Prolift®?

14 BY MR. MAZIE:

15 Q. Yes.

16 A. No.

17 Q. What about for any studies, based on
18 studies of the overall surgical population --

19 A. Right.

20 Q. -- from different surgeons, do you
21 have an opinion as to what the mesh exposure rate
22 has been for implantation of the Prolift®?

23 A. I've looked at the data on this
24 several different ways. And when you stratify it
25 based on case volume, so not so much

1 location/geography of a center or the hospital here
2 or there, but you really stratify it based on case
3 volume, that if a surgeon has done greater than 100
4 cases, the exposure rate averages approximately 4 to
5 percent.

6 Q. Okay.

7 What if a surgeon has done between 50
8 and 100 cases, what's their exposure rate?

9 A. It's slightly more than that. And
10 then if you're under 50, it's, again, even slightly
11 higher. I don't have the numbers off the top of my
12 head.

13 Q. Where are you getting this from?

14 A. A study done by Halligan, I think.
15 It was a large series -- it was a -- this was a net
16 analysis of all the publications of all the
17 transvaginal meshes done in peer-reviewed journals.
18 And they looked at two adverse outcomes, pain,
19 dyspareunia and exposure. And they did sort of a
20 metaanalysis of that. And then I went into that raw
21 data on that metaanalysis where they had a table,
22 all the numbers and case volume. And then I did
23 that stratification myself.

24 And the interesting -- I thought it
25 was very interesting -- is that I analyzed it two

1 ways. Every single surgeon in that stratification,
2 and it didn't trend down as sequentially. And then
3 I looked, which to me didn't make sense that it
4 should trend down sequentially, so I looked closer
5 at the data. And there are two individuals that
6 were -- two individual authors were significant
7 outliers that had very high exposure rates, so they
8 were -- if you take the outliers out, then the
9 trending was very sequential, that the more cases
10 the surgeons did, the better they became at it. And
11 when they crossed into the region of greater than
12 100, they had a very acceptable exposure rate.

13 Q. What do you consider to be an
14 acceptable exposure rate?

15 A. I would say, you know, acceptable is
16 around 4 to 6 percent, which is compatible with
17 transabdominal exposure rates, when the vagina is
18 open.

19 Q. Doctor, do you know what the exposure
20 rate is for someone who has had less than ten
21 surgeries that he's performed?

22 A. I couldn't -- not unless that person
23 has published. It would be depending on the
24 individual.

25 Q. Let me step back.

1 A. Okay.

2 Q. I'll withdraw that question.

3 You've given us some exposure --

4 You have an exposure rate of 4 to

5 5 percent for surgeons who have done more than 100

6 Prolift® surgeries. Correct?

7 A. That's been reported in the
8 literature, yeah.

9 Q. Okay.

10 What is the exposure rate for
11 surgeons who have performed less than ten Prolift®
12 procedures?

13 MR. SNELL: Objection, form.

14 THE WITNESS: I don't know of any
15 reports that reported on people who have done less
16 than ten, so I couldn't answer that.

17 BY MR. MAZIE:

18 Q. Do you know what the exposure rate is
19 for surgeons who have done less than 20 Prolift® or
20 other transvaginal mesh procedures?

21 MR. SNELL: Same objection.

22 THE WITNESS: Anecdotally, again, I
23 have physicians talk to me about their experiences
24 and their case files. So when I have had
25 physicians, you know, call me or talk to me in the

1 hallway at a conference room, they say, you know,
2 they're doing great with Prolift®, they've done
3 about 20 or 30 or 40 or 10, and they say, well, you
4 know, I'm doing great, my exposure rate is X, Y or
5 Z. And that, for the most part, has been favorable.
6 I have not had individuals come up to me and say,
7 geez, I've done 15 and I've got a 25 exposure rate,
8 because I know that would be a very memorable
9 conversation in my mind, saying, well, then I
10 suggest you stop doing them.

11 So, I -- you know, I'm very much
12 disappointed by hospitals and various places where
13 physicians are performing surgery, and if they're
14 having, you know, an outlier complication rate
15 that's not consistent with their peers, that either
16 they don't cease and desist on their own or that
17 someone else suggests that they get further
18 training.

19 So I have never had a conversation
20 with someone that has any volume and says, well, I
21 think I've got a 25 percent exposure rate.

22 BY MR. MAZIE:

23 Q. What's an unacceptable exposure rate
24 for mesh exposure after implantation of the
25 Prolift®?

1 MR. SNELL: Objection, form.

2 THE WITNESS: I think that -- I
3 think, in my estimate, it's a very difficult
4 question to answer, because the rate implies it's
5 only a quantitative metric in terms of -- you know,
6 of having it or not having it and the implication to
7 the patient. Because the fortunate thing about
8 exposures is that when a patient does have it, most
9 of them are completely asymptomatic, so they have no
10 symptoms whatsoever. And for those that do have
11 symptoms, their symptoms are very mild. They tend
12 to be a discharge and some spotting, or maybe if
13 they're sexually active, the husband may have a
14 sensation of a foreign body. So the exposure,
15 fortunately, clinically, has not been very
16 significant to the patient, and it's also been well
17 and easily managed, more often in the office,
18 sometimes nonsurgically, which is a topical cream.

19 So when we talk about exposures in
20 terms of an acceptable rate, I tend to use the gold
21 standard of an abdominal sacrocolpopexy. And
22 depending on which cohort, again, that you read, you
23 look at Ingrid Nygaard's work, and she did a very
24 large series looking at the various different
25 synthetic materials and the various types of

1 incisions, that it can get as low as 3 percent.

2 So I think our goal is 3 percent. I
3 think you need to look at factors that -- maybe once
4 you get above 10 percent, you need to start looking
5 at factors that you can modify to get lower than
6 that.

7 So the goal and acceptable rate to me
8 is around a 3 to 6 percent range. And when you get
9 above -- you get into 10 percent, you should be
10 thinking about it. You get to 15 or 20 percent,
11 then there's something that definitely can be done
12 and it shouldn't be that high.

13 BY MR. MAZIE:

14 Q. All right.

15 Do you agree that if somebody has a
16 15 percent erosion rate, that they should not be
17 performing the Prolift® surgery?

18 MR. SNELL: Objection, form.

19 BY MR. MAZIE:

20 Q. It's unacceptable?

21 MR. SNELL: Objection, form.

22 BY MR. MAZIE:

23 Q. As a rate?

24 MR. SNELL: Same objection.

25 THE WITNESS: Personally, I would